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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,448	12/28/2001	Tracee E.J. Eidenschink	29985/01-180	9310

4743 7590 04/27/2006

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,448

Applicant(s)

EIDENSCHINK, TRACEE E.J.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40, 52-55, 57, 58, 64-67, 69, 70, 76 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 2-16, 18, 23-38, 40, 53-55, 58, 65-67, 70, 76 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 19-22, 39, 52, 57, 64 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply received on 3/27/2006.
2. In the reply the Applicant amended claims 1, 20, 35, 52, and 64 have been amended. Claims 41-51, 56, 59-63, 68, 71-75 have been cancelled. Claims 76 and 77 are newly added claims containing no new matter and being drawn to a non-elected species.
3. Thus, claims 1-40, 52-55, 57-58, 64-67, 69-70, and 76-77 are pending in this application.
4. Of the pending claims, claims 2-16, 18, 23-38, 40, 53-55, 58, 65-67, and 70 have been previously withdrawn.
5. The Applicant has submitted new set of replacement drawings in the reply on 3/27/2006 and they have been considered and the previous objection has been withdrawn.

Election/Restrictions

6. Applicant's addition of newly added claims 76 and 77 in the reply filed on 3/27/2006 is acknowledged. Claim 76 and 77 are further withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 17, 20, 22, 39, 64 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Stivland et al (6102890). Stivland et al discloses a balloon catheter capable of being used as a stent delivery system (Fig 1; col 1, lns 13-35) having a hypotube (32) with a tubular shaft having a lumen (col 3, lns 64-67) and a main section integrally connected to a distal section (Fig 2), the distal section having a first section (144) connected to the main section (32) and a second section (138; Fig 2), the first section further having at least 1 slit (238; Fig 4; col 5, lns 27-29) extending at least partially and circumferentially around the tubular wall in close proximity to the second section that comprises an elongated solid stinger (248, Fig 4) that is tapered (246) and formed by a portion of the tubular wall (Figs 2, 4).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 19, 21, 52, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivland et al in view of Happ et al (6575958). Stivland et al discloses the invention substantially as claimed except for the second section comprising an elongated solid stinger formed by an elongated axial cut-out along the tubular wall. Happ et al teaches that it is known to have a solid hypotube (94) with an elongated cut-out in the axial direction along the tubular wall (Fig 1, 118) for the purpose

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of providing the transition (118) with greater flexibility than the proximal section to improve resistance to kinking while increasing flexibility. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end of the hypotube as taught by Stivland with the elongated axial cut-out as taught by Happ et al for the purpose of providing the transition with greater flexibility than the proximal section to improve resistance to kinking while increasing flexibility.

Response to Arguments

4. Applicant's arguments filed on 3/27/2006 have been fully considered but they are not persuasive.

5. The Applicant amended pending independent claims 1, 20, 52, and 64, adding the limitation "an elongated, solid stinger." The Applicant argues that Stivland et al does not disclose or suggest such a structure. Furthermore, the Applicant argues, "because the distal end of the hypotube is hollow, it cannot be solid as specified in the claims" (Remarks, pg 13, paragraph 1). Thus, Stivland et al fails to disclose or suggest that a hypotube with a solid stinger and hence a prima facie case of obviousness has not been established.

6. In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the stinger as having a solid cross-section" (Remarks, pg 12, paragraph 6); and "because the distal end of the hypotube is hollow, it cannot be solid as specified in the claims" (Remarks, pg 13, paragraph 1)) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the

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specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Stivland et al does disclose an elongated, solid stinger (248, Fig 4; see also Stivland et al's definition of hyptotube on col 3, Ins 64-67). If the Applicant wishes to recite the stinger having a cross-section that is solid, ie - having no conduit, the Examiner suggests reciting the limitations in the claims. As the claims currently read, the elongated stinger of Stivland et al is a solid.

7. The Applicant also argues that the rejection of claims 19, 21, 52, and 57 under 35 U.S.C. 103 (a) as being obvious over Stivland et al in view of Happ et al is improper. The Applicant argues that there is no motivation to combine Stivland et al and Happ et al (Remarks, pg 14, paragraph 2), that "the Examiner incorrectly states that Happ teaches the use of a cut-out to improve flexibility" (Remarks, pg 15, paragraph 2), and the proposed combination would render the Stivland device unsatisfactory for its intended use.

8. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Happ et al teaches an improved transition between a proximal shave portion and a more flexible distal shaft portion that provides enhanced flexibility and kink-resistance (col 2, Ins 19-

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23). The improved transition is disposed between proximal and distal shaft sections the improved kink resistance has been achieved by minimizing the differential in bending stiffness at the troublesome regions between the two sections (col 2, lns 41-43, 46-49). The proximal shaft section (16) has a hypotube (94). A distal tip (115) of the hypotube (94) is tapered distally to a smaller traverse dimension and is generally between 4-8 cm long (col 5, lns 25-29). The transition (118) includes the proximal portion of the distal shaft section (19) and the distal portion of the proximal shaft section (16) to provide for a smooth transition between the relatively rigid proximal shaft section and the relatively flexible distal shaft section (col 5, lns 31-34). The transition (118) further includes a tubular support member (130) that is formed and constructed to provide the transition (118) with greater flexibility than the relatively more rigid proximal shaft section (16) (col 5, lns 40-43). Happ et al discloses multiple embodiments of the length of the hypotube tapered tip (115), transition (118), junction (202), and the tubular support member (130) (see Figs 1-19). The multiple embodiments have different lengths and placements of the components to minimize the bending stiffness differential as well as increasing the overall flexibility of the catheter (col 2, lns 43-45). The multiple lengths and placement of the tapered tip (115) of the hypotube in the transition (118) in combination with the recited purpose of minimizing the bending stiffness differential as well as increasing the overall flexibility of the catheter provide a teaching to one of ordinary skill in the art that the hypotube (94) with an elongated cut-out in the axial direction along the tubular wall (115, Fig 1, 118) serves the purpose of acting as a resistance to kinking in the transition while improving flexibility in the transition over the rigid proximal distal section via the

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elongated cutout in the axial direction along the tubular wall. Thus, the Examiner finds motivation to modify the distal end of the hypotube as taught by Stivland with the elongated axial cut-out as taught by Happ et al for the purpose of providing the transition at the distal end of the hypotube of Stivland with greater flexibility than the proximal section while still keeping resistance to kinking.

9. In response to applicant's argument that the proposed combination would render the Stivland device unsatisfactory for its intended use, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the elongated cut-out in the axial direction along the tubular wall of Happ et al may be bodily incorporated into the distal end tip of the hypotube of Stivland et al (see discussion in preceding paragraph).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

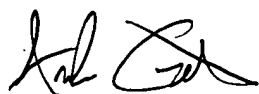
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN SIRMONS
PRIMARY EXAMINER

